## Text of the Second Office Action

Gleiss & Große
Gleiss & Große
Gleiss Große Schiell & Parmer
Patientanwähre Rechtsanwähre

2 1. APR, 2008

Application Number: 200480016063.0

The examiner studied the observation submitted by the applicant on Aug. 8, 2007, and the opinions are as follows:

1. Claim 1 requested to protect the use of the mixture of 1,6-GPS and 1,1-GPM as a prebiotic. The reference Liu Tangsen & Li Haibin. The natural new-type sweetening agent - Palatinose and Palatinitol, G.X. Light Ind. 2001, Vol.2: 16~18) published that palatinitol (isomalt) is an equimolar mixture of α-1,6-GPS and α-1,1-GPM as a food ingredient which has a good hygroscopic and deliquescent performance, can be highly tolerated by human bodies (causing a low diarrhea possibility), have a low energy content and a low digestion absorption rate, and is not easy to result in negative responses such as abdominal distension, borborygmus and so on, and the majority of palatinitol is utilized in the ferment by the intestinal microorganisms in the large intestines to be degraded to small molecular organic acids, CH4, CO2, H2 and so on (Please refer to Pages 16~18 of the reference 1). Thus the reference 1 has published a mixture same as that in the claim 1 of the present application, and the characteristics of the mixture are that the majority of the mixture can not be absorbed by human bodies and is degraded by the intestinal microorganisms in the large intestines to be compositions such as small molecular organic acids and so on, i.e. the reference 1 disclosed the characteristics and the potent use of the mixture. The difference between claim 1 of the present application and the reference 1 is: claim 1 defines the use of the mixture as "a prebiotic", but the reference 1 did not nail down this point, and only explained the nondigestible characteristic of the mixture. The reference 2)(Hu Xuezhi, Probiotic bacteria, prebiotics and their health functions and safeties, Shanghai Medical and Pharmaceutical Journal, 2001, Vol.22(8): 356~358) published the definition of prebiotics and the normal prebiotics, and pointed out that though most of oligosaccharides and sugar alcohols can not be absorbed by human bodies, they can be absorbed selectively by the beneficial intestinal flora in the intestines of human bodies to produce various small molecular organic acids to lower the pH of the intestines to suppresses the production of corrupt products like toxins or carcinogens such as alkaline NH<sub>3</sub>, H<sub>2</sub>S, amides, indoles and so on, to improve the growth of the beneficial bacteria such as lactobacilli and bifidobacteria in human bodies to adjust the intestinal flora to prevent them from maladjustment and disorder, so these oligosaccharides and sugar alcohols are called "prebiotics" (please refer to the last paragraph of Volume 1 of Page 356, and Paragraphs 3 and 6 of Volume 2 of Page 357 of the reference 2). The references 1 and 2 belonged to the application field of sugar alcohols, and the reference 2 presented the inspiration of sugar alcohols used as prebiotics, then based on the characteristics of the mixture provided by the reference 1, the technicians skilled in the art would choose the sugar alcohol-isomalt as a prebiotic, and it is a simple selection. Based on the reference 1 and reference 2, through a simple selection, the technicians skilled in the art can obtain the use of the mixture (i.e. isomalt) of 1,6-GPS and 1,1-GPM as a prebiotic claimed by claim 1 of the present application. Based on the references 1 and 2, claim 1 of the present application does not have inventiveness, and is not in conformity with the provisions of Article 22, paragraph 3 of the Patent Law.

SUCHORAL BUTOTA ENIBAT

#4414 F. UU3 / UU

2. Based on claim 1, claims 2, 3, 7 and 8 further defined that the mixture can be used as a bifidogenic (bifidusfactor) prebiotic or a butyrogenic substrate or the sole prebiotic, which are different from the reference 1. Combined with the comments on claim 1, these further limitations can be obtained just by conventional measurements and researches about the prebiotic performance and the metabolites of the mixture done by the technicians skilled in the art, and also do not bring unexpected technical effects to said uses. Therefore, these further definitions are simple selections of the technicians skilled in the art;

Claims 4~6, 9~10 and 14 made further limitations, but these limitations have been published by the reference 1, and there are no new differences compared with the reference 1:

Claims 11~13 and 15~19 further defined that the mixture further comprises other non-hydrogenated oligosaccharides / prebiotics / dietary fibres / nondigestible carbohydrates / prebiotic bacteria / synbiotics formed with the mixture of claim 1, and so on, which are conventional hygienical compositions having prebiotic roles, thus it is a simple selection to add these compositions to prebiotics in the related field;

Therefore, based on the references 1 and 2, through simple selections, the uses claimed by claims 2~19 can be obtained. Claims 2~19 neither have prominent substantive features nor represent a notable progress, thus they do not have inventiveness regulated by the

## 008862151502559

## provisions of Article 22, paragraph 3 of the Patent Law.

- 3. Claims 20 and 21 further defined the forms of the mixture, and claims 24~34 further defined that the mixture can be used to manufacture pharmaceuticals to help the intestinal flora metabolize to realize various hygienical functions. In the related field, it is simple to choose the form (such as solid/liquid or suspension) of the mixture which does not provide unexpected technical effects to its functions. And various intestinal hygienical functions (such as treat and/or prevent intestinal disorder, recover and/or stabilize healthful intestinal flora, suppress the growth of harmful bacteria, prevent overproduction of toxic and harmful substances, and so on) that the prebiotics have are known to the technicians skilled in the art actually. Thus it is a simple selection to obtain the detailed pharmacological functions (such as the detailed experimental parameters in treating intestinal disorder and stabilizing intestinal flora) that this prebiotic has by further studying, which do not produce unexpected technical effects. Therefore combined with the comments on claims 1-19, it is obvious to obtain the technical solutions claims 20~21 and 24~34 requested to protect based on the references 1 and 2, thus claims 20~21 and 24~34 do not have inventiveness regulated by the provisions of Article 22, paragraph 3 of the Patent Law.
- 4. Claim 22 further defined that the mixture can be used to manufacture human food or other articles consumption or animal feed, and Claim 23 further defined that the mixture can be used to manufacture pharmaceuticals, which are conventional uses of the prebiotics and are known to the technicians skilled in the art, and they are simple selections of the technicians skilled in the art. Therefore combined with the comments on claim 1, it is obvious to obtain the technical solutions of claims 22~23 based on the references 1 and 2. Claims 22~23 do not have inventiveness regulated by the provisions of Article 22, paragraph 3 of the Patent Law.
- 5. Claim 35 further defined the forms of the products with the mixture, and claims 36~46 further defined the detailed functions of the mixture. It is a simple selection in the related art to choose different forms of the products, which are just different carriers and do not affect these products substantially, and various intestinal hygienical functions that the prebiotics have are known to the technicians skilled in the art, thus it is a simple selection to obtain the detailed pharmacodynamical parameters by further studying, which do not produce unexpected technical effects. Therefore combined with the comments on claims 1~34, it is obvious to obtain the technical solutions claims 35~46 requested to protect based

008862151502559

on the reference 1, thus claims 35-46 do not have inventiveness regulated by the provisions of Article 22, paragraph 3 of the Patent Law.

Based on the above-mentioned reasons, no patent right shall be granted to the present application. At the same time, the specification of the present application did not state other contents having inventiveness, thus there is no prospect for the present application to be granted the patent right. If the applicant can not state sufficient reasons that the present application has inventiveness within the time limit stated in this notification, the present application will be rejected according to the provisions of Rule 53 of the Implementing Regulations and the provisions of Article 38 of the Patent Law.

The examiner: PAN, Ke
The number: 4623